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PPLICATION NO.	FII	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/508,661	0	5/26/2000	JEAN-PIERRE SACHETTO	6789 EXAMINER	
2292	7590	01/28/2004			
		KOLASCH & BII	GEORGE, KONATA M		
PO BOX 747 FALLS CHURCH, VA 22040-0747				ART UNIT	PAPER NUMBER
	,		1616		

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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	Application No.	Applicant(s)					
	09/508,661	SACHETTO ET AL.					
Office Action Summary	Examiner	Art Unit					
	Konata M. George	1616					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
1)⊠ Responsive to communication(s) filed on <u>15 Oc</u>	ctober 2003						
	action is non-final.						
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) <u>1-3,6,15,22-27,33,37-39,42,43 and 45-55</u> is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5)⊠ Claim(s) <u>1-3,6,15, 37-39, 42, 43 and 45</u> is/are allowed.							
6)⊠ Claim(s) <u>22-27,33 and 46-55</u> is/are rejected.							
7) Claim(s) <u>23</u> is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement.						
Application Papers							
9) The specification is objected to by the Examiner.							
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. §§ 119 and 120							
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the priori application from the International Bureau * See the attached detailed Office action for a list of 13) Acknowledgment is made of a claim for domestic since a specific reference was included in the first 37 CFR 1.78.  a) The translation of the foreign language provi	have been received. have been received in Application ty documents have been received (PCT Rule 17.2(a)). of the certified copies not received priority under 35 U.S.C. § 119(e) t sentence of the specification or visional application has been received.	on No d in this National Stage d. l) (to a provisional application) in an Application Data Sheet.					
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.							
	The same and the s						
Attachment(s)							
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) Notice of Informal Pa	(PTO-413) Paper No(s) atent Application (PTO-152)					

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#### **DETAILED ACTION**

Claims 1-3, 6, 15, 22-27, 33, 37-39, 42, 43 and 45-55 are pending in this application.

#### **Action Summary**

- 1. Examiner acknowledges the cancellation of claims 5, 7-14, 16-21, 28, 29, 32, 35, 36, 40 and 41 and the addition of claims 53-55. Therefore, all rejections directed towards cancelled claims are hereby withdrawn.
- 2. The rejection of claims 30 and 33 under 35 U.S.C. 102(b) as being anticipated by Slagel is hereby withdrawn.
- 3. The rejection of claims 30, 33 and 37 under 35 U.S.C. 103(a) over Slagel is hereby withdrawn.

#### Restriction/Election

4. Claims 8, 10, 12-14, 28-30, 32, 33, 36, 37, 40 and 41 are directed to an allowable product. Pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86), claims 1-3, 6, 15, 22-27, 38, 39, 42 and 43, directed to the process of making or using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, are now subject to being rejoined. Claims 1-3, 6, 15, 22-27, 38, 39, 42 and 43 are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Since all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, the restriction requirement made is hereby withdrawn.

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#### Claim Objections

5. Claim 23 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 23 depends upon a later claim (claim 33), which is improper.

## Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 22-27, 33 and 46-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph have been described in *In Re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it

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is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

### (1) The nature of the invention:

The invention is directed towards the treatment of prophylaxis (i.e. prevention) of inflammatory bowel disease (IBD) comprising disease mucosa of the gastrointestinal tract with a therapeutic amount of a polysaccharide.

#### (2) The state of the prior art:

The prior art teaches using polysaccharides in compositions to treat IBD however, not as the sole therapeutic agent.

(3) The relative skill of those in the art:

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art:

The art pertaining to the prophylaxis of IBD remains highly unpredictable. While it is known to treat IBD the prophylaxis however, is not.

(5) The breadth of the claims:

The claims are narrow.

(6) The amount of direction or guidance presented:

The specification provides direction or guidance by way of examples with respect to treating IBD however, not for the prophylaxis of IBD.

(7) The presence or absence of working examples:

The specification provides direction or guidance by way of examples with respect to treating IBD however, not for the prophylaxis of IBD.

(8) The quantity of experimentation necessary:

The specification did enable any person skilled in the art to which it pertains to use the invention commensurate in scope with this claim. The skilled artisan would have numerous factors to consider when trying to prevent IBD.

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Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Konata M. George, whose telephone number is

(703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday

to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers

for the organization where this application or proceeding is assigned are (703) 308-4556

for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the receptionist whose telephone number is

(703) 308-1235.

Konata M. George

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

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